PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: **WO 98/58600**

(43) International Publication Date: 30 December 1998 (30.12.98)

(21) International Application Number: PCT/EP98/04003

(22) International Filing Date: 17 June 1998 (17.06.98)

(30) Priority Data:
97/07694 20 June 1997 (20.06.97) FR

(71) Applicant *(for all designated States except US)*: LABORATOIRES NYCOMED S.A. [FR/FR]; Centre d'Affaires et d'Activités Tolbiac–Massena, 25, quai Panhard et Levassor, CE No.19, F–75644 Paris Cedex 13 (FR).

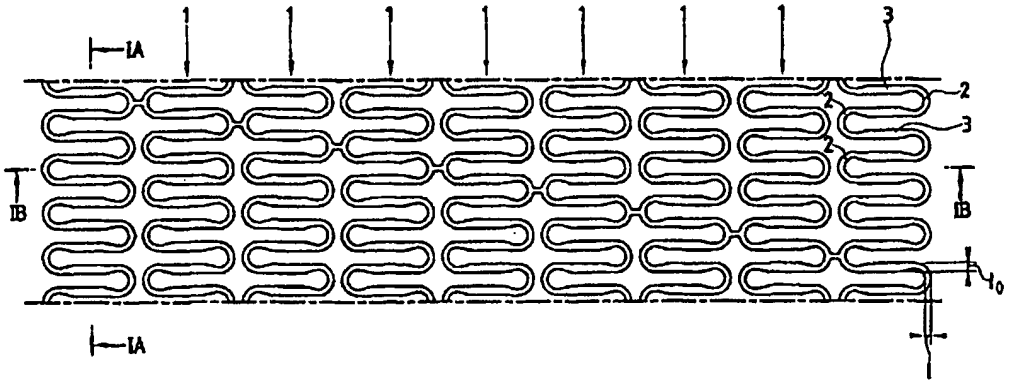
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: HILAIRE, Pierre [FR/FR]; 25, rue Pierre Semard, F–75009 Paris (FR). PAYROU, Viviane [FR/FR]; 4, impasse du Bois Briard, F–94800 Villejuif (FR).

(74) Agents: HUBERT, Philippe et al.; Cabinet Beau de Loménie, 158, rue de l'Université, F–75340 Paris Cedex 07 (FR).

(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: EXPANDABLE STENT WITH VARIABLE THICKNESS



(57) Abstract

The present invention relates to an expandable tubular device for implantation in the lumen of a body duct, such as a blood vessel in particular, in order to ensure a passage therein, said device consisting of an assembly of tubular elements aligned along a common longitudinal axis and successively joined together in pairs by a plurality of linking members, each tubular element consisting of a strip forming a zigzag corrugation defining bent extreme portions which are successively connected together in pairs in opposite directions by rectilinear intermediate portions, the thickness (e) of said strip forming each of the above–mentioned tubular elements (1), measured radially relative to said tubular element, being greater than the width l of this strip in said bent portions (2).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

EXPANDABLE STENT WITH VARIABLE THICKNESS

The present invention relates in general terms to an expandable tubular device for implantation in the lumen of a body duct in order to ensure a passage therein.

This invention applies mainly to the field of the treatment of blood vessels exhibiting stenoses, and more generally to the field of the treatment of diseases of various anatomical ducts of the human or animal body, such as, for example, the urinary ducts. especially the urethra, or else the digestive ducts, especially the esophagus.

The percutaneous implantation of an expandable tubular device, commonly designated by the American term stent, in a stenotic blood vessel is generally recommended. for example after a conventional angioplasty, for preventing the dilated vessel from closing up again spontaneously or for preventing its occlusion by the formation of a new atheromatous plaque and the possible recurrence of stenosis.

Document EP 0540290, in particular, discloses an expandable tubular device in the form of a stent; in general terms it consists of an assembly of radially expandable, tubular elements aligned along a common longitudinal axis and successively joined together in pairs by a plurality of linking members.

Each of the above-mentioned tubular elements consists of a strip forming a zigzag corrugation defining bent extreme portions which are successively connected together in pairs in opposite directions by rectilinear intermediate portions.

As can be seen, by virtue of this zigzag conformation, such a device is expandable between a first, constricted state, enabling it to be implanted percutaneously by means of an insertion device of reduced diameter, and a second, expanded state, in which said device makes it possible to ensure a passage in the lumen of the body duct.

The expandable device described in said document of the prior art is inserted by means of an angioplasty balloon-tip catheter.

For this purpose said device is placed in the constricted state on the balloon, the latter being inflated at the point of release in order to cause said device to dilate.

It has been observed that the expansion of the device described in the above-mentioned document does not occur uniformly, the symmetry of said

device being in itself insufficient to distribute the deformation forces exerted thereon during the inflation of the balloon.

A particular consequence of the non-uniform expansion of the device described in the above-mentioned document, which is due especially to the absence of distribution of the radial forces exerted thereon, is that it does not allow a passage of constant dimensions to be obtained in the body duct, so this type of device is not entirely satisfactory.

Under these conditions the object of the present invention is to solve the technical problem consisting in the provision of a novel design of expandable tubular device which guarantees a uniform expansion, especially during the inflation of a balloon used to insert it, and a good distribution of the radial forces exerted thereon after its insertion, and which thus makes it possible to obtain a constant passage in the body duct to be treated.

The solution to this technical problem, according to the present invention, consists of an expandable tubular device for implantation in the lumen of a body duct, such as a blood vessel in particular, in order to ensure a passage therein, said device consisting of an assembly of tubular elements aligned along a common longitudinal axis and successively joined together in pairs by a plurality of linking members, each tubular element consisting of a strip forming a zigzag corrugation defining bent extreme portions which are successively connected together in pairs in opposite directions by rectilinear intermediate portions, wherein the thickness of said strip forming each of the above-mentioned tubular elements, measured radially relative to said tubular element, is greater than the width of this strip in said bent portions.

Thus, as can be seen, the novelty of the proposed solution lies in the fact that the distribution of the deformation forces during the expansion of the device is optimized by adjusting, at least in certain portions constituting each tubular element of the device, the thickness/width ratio as a function of the forces exerted thereon.

The fact that the thickness is relatively greater than the width in the above-mentioned bent portions actually makes it possible to favor a uniform expansion of the device, as it is precisely these zones which are subjected to the highest radial stresses during the inflation of the balloon.

Advantageously, to further optimize the distribution of the forces exerted on the device, both during its insertion and in the use position, the thickness of the

strip forming each of the above-mentioned tubular elements will be less than the width of this strip in the rectilinear portions.

Again advantageously, the thickness of the strip constituting each tubular element is less in the rectilinear portions than in the bent portions, whereas the width of the strip constituting each of the above-mentioned tubular elements is greater in the rectilinear portions than in the bent portions.

The invention will be better understood, and other objects, characteristics and advantages thereof will become more clearly apparent, from the following explanatory description referring to the attached schematic drawings, which are given solely by way of non-limiting examples illustrating two currently preferred embodiments of the invention, and in which:

- Figure 1 is a two-dimensional view of the evolute of the lateral surface of a device according to a first embodiment of the invention, corresponding to the constricted state of this device;

- Figure 1A is a cutaway view along the line IA-IA of Figure 1, showing the thicknesses of the different constituent parts of the device;

- Figure 1B is a cutaway view along the line IB-IB of Figure 1, again showing the thicknesses of the different constituent parts of the device;

- Figure 2 is a two-dimensional view similar to Figure 1 of a device according to a second embodiment of the invention;

- Figure 2A is a cutaway view along the line IIA-IIA of Figure 2, showing the thicknesses of the different constituent parts of the device; and

- Figure 2B is a cutaway view along the line IIB-IIB of Figure 2, again showing the thicknesses of the different constituent parts of the device.

Figures 1 and 2 therefore show an expandable tubular device according to the present invention which, for the clarity of the description, is shown in a plane configuration corresponding to the evolute of its lateral surface.

In general terms this device consists of an elongate, approximately tubular body or frame defined by a plurality of tubular elements 1 (nine in the example shown in Figure 1 and five in the example shown in Figure 2) aligned along a common longitudinal axis and successively joined together in pairs by a plurality of linking members, which will be described in greater detail below.

Each tubular element 1 consists of a strip forming a zigzag corrugation defining bent extreme portions 2 which are successively connected together in pairs in opposite directions by rectilinear intermediate portions 3.

Advantageously, for a given tubular element, the rectilinear portions 3 are all of the same length and the bent portions are all identical and approximately form a semicircle. Thus the above-mentioned corrugation advantageously has a uniform shape.

As can be seen especially in Figures 1A and 2A, the thickness e of the strip forming each tubular element 1 in the bent portions is greater than the width l of this strip in said bent portions.

The thickness in this context is as measured radially relative to said tubular element.

As can be seen, the novelty of the present invention compared with the known state of the art lies in the fact that, in the bent portions, the device is given a particular profile (thickness greater than width) which ensures that these bent portions behave well when they are subjected to the radial forces exerted during the expansion of the tubular elements.

In the example shown in Figures 1, 1A and 1B, the thickness e_0 of the strip forming each tubular element 1 in the rectilinear portions 3 is approximately equal to the thickness e of said strip in the bent portions 2.

Advantageously, the width l_0 of the above-mentioned strip in the rectilinear portions 3 is greater than the width l of said strip in the bent portions 2.

By way of example, the thickness e in the bent portions will be of the order of 0.15 mm and the width l of the order of 0.10 mm.

Likewise, both the thickness e_0 and the width l_0 in the rectilinear portions will be of the order of 0.15 mm.

In the embodiment shown in Figures 2, 2A and 2B, the thickness e_0 of the strip forming each tubular element 1 in the rectilinear portions 3 is less than the thickness e of said strip in the bent portions.

Moreover, in this case, the thickness e of the strip is greater than the width l as far as the bent portions 2 are concerned, whereas the thickness e_0 of the strip is less than the width l_0 as far as the rectilinear portions are concerned.

By way of example, the thickness e in the bent portions will be of the order of 0.15 mm and the width l of the order of 0.10 mm.

Likewise, the thickness e_0 in the rectilinear portions will be of the order of 0.10 mm, whereas the width l_0 will be of the order of 0.15 mm.

According to one particular characteristic common to both embodiments of the invention, the thickness and width transitions between the rectilinear portions

3 and the bent portions 2 will be gradual in order to avoid the formation of an incipient fracture.

The linking members which successively join the tubular elements 1 together in pairs can have a very wide variety of configurations.

In general terms these linking members will be arranged so as to be angularly spaced apart and coplanar with the tubular elements 1.

In their simplest conformation, these linking members can consist of rectilinear flat portions, as shown in Figure 1.

Preferably, however, because of the particular conformation of the tubular elements 1, the linking members will be capable of being extended along the longitudinal axis so as to compensate for the decrease in length of the tubular elements 1 during their radial expansion, as shown in Figure 2.

In general terms these linking members will consist of a strip, preferably of the same width as the bent portions 2, forming a zigzag corrugation also defining bent portions which are successively joined together in pairs in opposite directions by rectilinear portions.

In the currently preferred embodiment shown in Figures 2, 2A and 2B, the linking members designated in general terms by the reference number 4 consist of a strip forming a corrugation defining three bent intermediate portions, said linking members 4 being joined at each end to a tubular element 1 via a portion 5, which is also bent.

These linking members give the device very great bending flexibility, which makes it easier to guide it inside the vascular system by enabling the existing bends and curves to be negotiated in the best possible manner.

The device which has now been described is therefore expandable between a constricted state, enabling it to be guided inside the lumen through a body duct, such as a blood vessel, for example, and an expanded state, in which said device, after a uniform expansion, comes into contact with the inner wall of the body duct, defining a passage of approximately constant diameter inside said duct.

This device will generally be forcibly expanded mechanically under the action of a force exerted radially outwards, for example under the effect of the inflation of a balloon.

It is obvious that such a device can also be of the "auto-expandable" type, i.e. capable of changing by itself from a first, constricted position under stress, enabling it to be guided through the body duct, to a second, expanded working position.

In general terms an expandable tubular device according to the present invention can be made of any material compatible with the body duct and the body fluids with which this device may come into contact.

In the case of an auto-expandable device, it will be preferable to use a material with a recovery capacity, selected for example from the group comprising stainless steel, Phynox® and nitinol.

In the case of a device with forced expansion, a material with a low elastic recovery capacity will be used, such as, for example, a metallic material like tungsten, platinum, tantalum or gold.

In general terms a device according to the invention can be obtained from a hollow tube with an approximately constant thickness corresponding to the desired thickness of the bent portions 2.

In the case of the embodiment shown in Figures 1, 1A and 1B, the final configuration of the device can be obtained either by laser cutting followed by electrochemical polishing, or by chemical or electrochemical treatment.

In the case of the device shown in Figures 2, 2A and 2B, the desired relief can be obtained by modifying the above-mentioned tube of constant thickness at the points where it is desired to reduce the thickness, i.e. at the points corresponding to the rectilinear portions 3.

The final configuration of the device can then be obtained either by laser cutting followed by electrochemical polishing, or by chemical or electrochemical treatment.

Such a device can also be obtained from a sheet of approximately constant thickness corresponding to the desired thickness of the bent portions 2.

This sheet can then be modified to reduce the thickness in the parts corresponding to the rectilinear portions 3.

The geometric configuration of the device can then be obtained either by laser cutting followed by electrochemical polishing, or by chemical or electrochemical treatment.

The sheet cut in this way is then rolled up to form a cylinder and welded to give the desired final structure.

The device which has now been described can be inserted in a manner known per se and reference may be made in this respect to the state of the art, especially document US 4,886,062.

In the case of a device with mechanically forced expansion, the insertion system will preferably comprise a balloon-tip catheter on which the device will be

positioned in the constricted state before being introduced into an insertion tube for guiding it to the site to be treated.

It should be noted that the device according to the invention can be used not only as a stent but also for the fixing of implants, particularly casings made of woven, non-woven or expanded porous polymers, or elastic membranes for the isolation of aneurisms.

CLAIMS

1. An expandable tubular device for implantation in the lumen of a body duct, such as a blood vessel in particular, in order to ensure a passage therein, said device consisting of an assembly of tubular elements aligned along a common longitudinal axis and successively joined together in pairs by a plurality of linking members, each tubular element consisting of a strip forming a zigzag corrugation defining bent extreme portions which are successively connected together in pairs in opposite directions by rectilinear intermediate portions, wherein the thickness (e) of said strip forming each of the above-mentioned tubular elements (1), measured radially relative to said tubular element, is greater than the width l of this strip in said bent portions (2).

2. A device according to claim 1 wherein the width (l_0) of the strip constituting each of the above-mentioned tubular elements (1) is greater in the rectilinear portions than the width (l) of said strip in the bent portions (2).

3. A device according to claim 1 or 2 wherein the thickness (e_0) of the above-mentioned strip is greater in the rectilinear portions (3) than the thickness (e) of this strip in said bent portions (2).

4. A device according to one of claims 1 to 3 wherein the thickness (e_0) of the above-mentioned strip in the rectilinear portions (3) is less than the width (l_0) of this strip in said rectilinear portions (3).

5. A device according to one of claims 3 or 4 wherein the thickness and width transitions between the rectilinear portions (3) and the bent portions (2) are gradual.

6. A device according to any one of the preceding claims wherein the above-mentioned bent portions (2) project radially outwards relative to said rectilinear portions (3) of the above-mentioned strip constituting each tubular element (1).

7. A device according to any one of the preceding claims wherein the above-mentioned linking members are angularly spaced apart and approximately coplanar with the above-mentioned tubular elements (1).

8. A device according to claim 7 wherein each of the above-mentioned linking members (4) consists of a strip forming a corrugation defining at least three bent portions which are successively connected together in pairs in opposite directions, and the free ends of which are respectively joined to two adjacent tubular elements.

FIG.1A

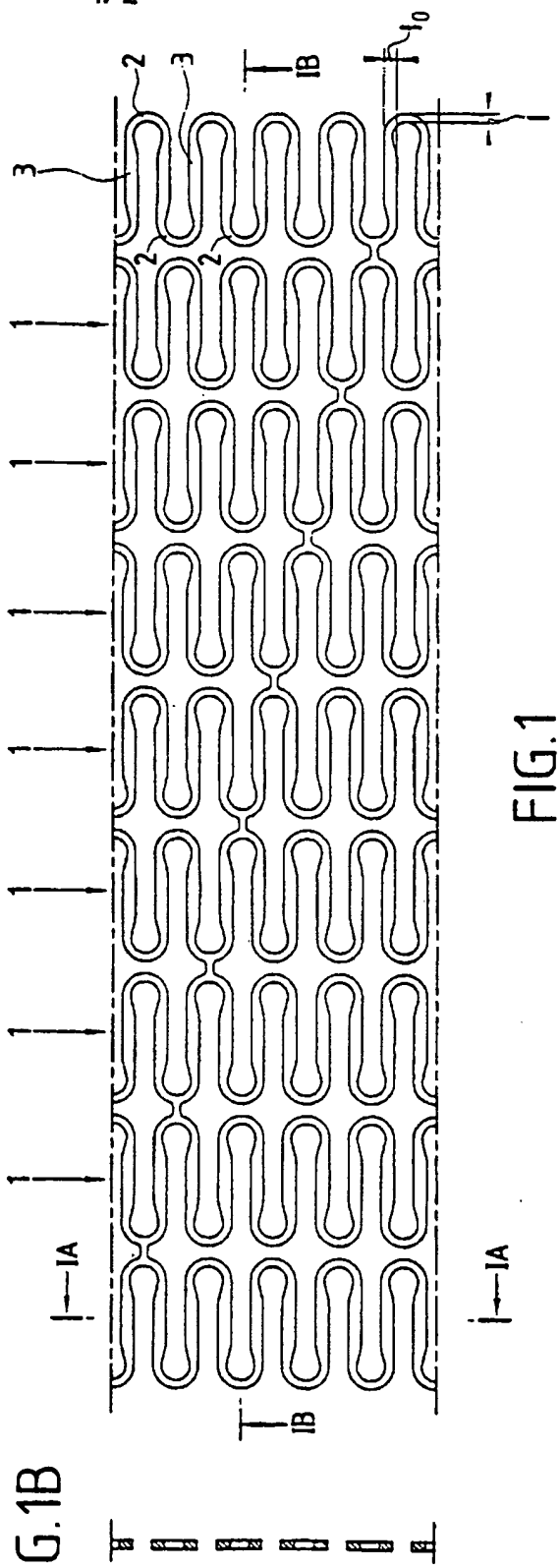


FIG.1

FIG.1B

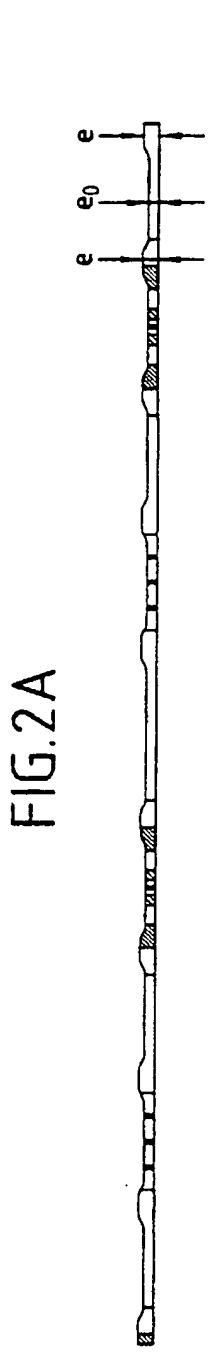


FIG.2A

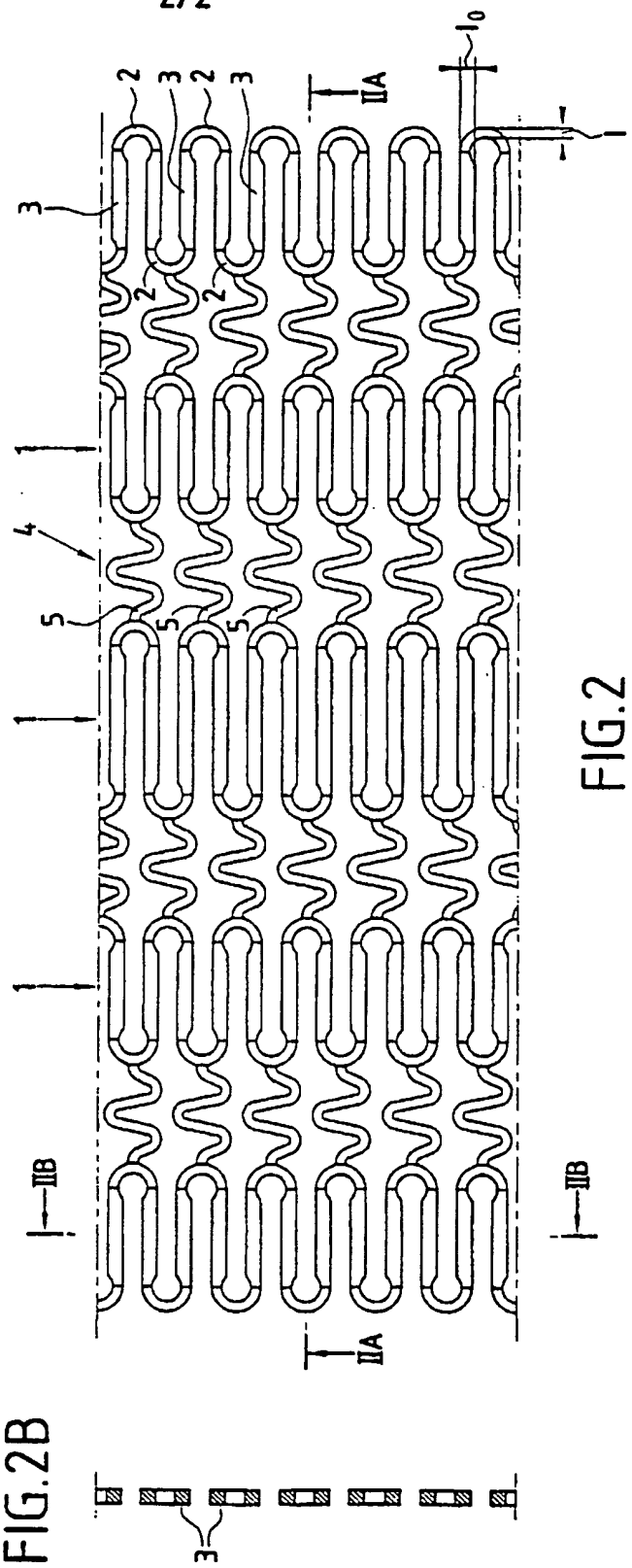


FIG.2

FIG.2B

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/EP 98/04003

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimumdocumentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 0 806 190 A (SORIN BIOMEDICA CARDIO S.P.A.) 12 November 1997 see figures 4-6	1-3
A	EP 0 540 290 A (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) 5 May 1993 cited in the application see the whole document	1
A	DE 195 37 872 A (ALT) 17 April 1997	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publicationdate of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of theinternational search	Date of mailing of the international search report
23 November 1998	01/12/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Smith, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter onal Application No
PCT/EP 98/04003

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 806190 A	12-11-1997	IT T0960373 A	10-11-1997
		IT T0960374 A	10-11-1997
		IT T0960375 A	10-11-1997
		IT T0960376 A	10-11-1997
		IT T0960377 A	10-11-1997
EP 540290 A	05-05-1993	CA 2079417 A	29-04-1993
		DE 69224262 D	05-03-1998
		DE 69224262 T	14-05-1998
		DE 540290 T	05-06-1997
		DE 734699 T	05-06-1997
		EP 0734699 A	02-10-1996
		EP 0807424 A	19-11-1997
		JP 2645203 B	25-08-1997
		JP 6181993 A	05-07-1994
		US 5421955 A	06-06-1995
		US 5514154 A	07-05-1996
		US 5603721 A	18-02-1997
		US 5728158 A	17-03-1998
		US 5735893 A	07-04-1998
		US 5766238 A	16-06-1998
DE 19537872 A	17-04-1997	NONE	